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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,668	06/29/2001	Masato Ohta	P21156	9364

7055 7590 03/16/2004

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EXAMINER	
GORDON, BRIAN R	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/893,668	OHTA ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-9-2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Interpretations

3. The microplate and containers have not been positively claimed as elements of the invention. However, several of the claimed elements are described in reference to the unclaimed elements. As such, the examiner interprets the phrases directed to the unclaimed elements, microplate and containers, as supporting material for clarity of the claims and intended use of the elements of the invention.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by McCulloch et al. US 5,122,342.

McCulloch disclose an apparatus wherein microtitre plates are on carriers having machine readable labels and wherein the samples of bio-fluid and reagent dispensers also preferably carry machine readable labels whereby the micro-processors which controls movement of the plates through the apparatus can verify correct operation thereof. Movement of the plates is effected by a plate carrier (tray) transfer mechanism (conveying mechanism) which has the ability to move the plate carriers in any order and in either direction along each of the x,y and z axes.

The apparatus has an input magazine generally indicated at 10 for plate carriers 11 each loaded with a microtitre plate 12, and an output magazine 13 which receives the carriers 11 after they have passed through the various operational stations of the apparatus.

Input magazine 10 defines a transfer station at which the wells of the plates are dosed with measured volumes of bio-fluid transferred thereto by a multi-head automatic pipette arrangement generally indicated at 14 and indexable along the x-axis on rails 15 between the transfer station and a sample receiving section 16 loaded with tubes 17 of sample. The arrangement 14 is also indexable along the y-axis so that the pipette tips

can register with any desired wells in a plate located on a carrier at the transfer station. The pipette tips are themselves movable along the z-axis as is obviously necessary for collection and delivery of sample.

Whilst the reagents are being dispensed the plate carriers remain supported by the fork which executes necessary step movements in the x and y directions.

The fork 20 then moves the plate carrier into an incubator 25 (temperature maintaining mechanism) and deposits it for the required residence time before collecting it for transfer to a washer 26 and reader 27 in turn. The incubator may have a variable heat control and may include a refrigerated zone, since it may be desired to carry out the colourmetric stage of some assays, for example the peroxidase catalysed cleavage of 3,3'5,5'-Tetramethylbenzidine Dihydrochloride, at temperatures below room temperature.

6. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Marquiss et al. US 20020009391.

Marquiss et al. discloses an integrated sample-processing system and components thereof for preparing and/or analyzing samples. The components may include a transport module (tray conveying mechanism), a fluidics module, and an analysis module, among others.

The device may include a cleaning module might include components for emptying and/or cleaning sample holders (sample tray). A sealing module might include components for sealing, unsealing, and/or otherwise covering and uncovering sample holders. An incubation module (temperature maintaining mechanism) might include

components for incubating sample holders and their associated samples, with environmental control of atmosphere, temperature, agitation, and so on. A sample preparation module might include components for particular sample-preparation functions, such as a thermocycler for performing heating and cooling during the polymerase chain reaction (PCR).

Incubation module 4300 also may include agitation elements such as a rocker for rocking, shaking, and/or otherwise agitating enclosed sample holders to mix or aerate associated samples.

Function modules generally include one or more function sites at which a corresponding function is performed. For example, a fluidics module may include a dispense site 712 at which a fluid is dispensed, an analysis module may include an examination ("exam") site 714 at which a sample is analyzed, and an auxiliary module may include an auxiliary site 716 at which an auxiliary function is performed, such as cleaning, sealing, storage, etc. A transport module may be connected directly or indirectly with I/O sites 702 for sample input and output, and with one or more of the function sites. If the transport module is connected indirectly to a function (or I/O) site, the transport module might hand off a sample holder at a transfer site to a separate transport mechanism associated with the respective function module. A transport module also may be connected to additional robotics for providing and removing sample holders from the I/O sites.

The sample holder comprises any substrate or material capable of supporting a sample so that the sample holder and associated sample can be transported by an

automatic transport module and subjected to a function such as fluid dispensing or optical analysis at a corresponding function module. Sample holders may be used alone, in stacks, or in combination with seals or covers, as described below. Sample holders may support samples at low, intermediate, or high density, and be designed for single or multiple use.

Frame 1202 is the main structural component of microplate 1200. The frame may have various shapes and various dimensions. In microplate 1200, frame 1202 is substantially rectangular, with a major dimension X of about 127.8 mm and a minor dimension Y of about 85.5 mm. Tolerances in plate dimensions typically are about .+-.0.5-1.0 mm for polystyrene plates, but may increase to about .+-.2 mm for polypropylene plates, especially if the polypropylene plates are produced using molds designed for polystyrene plates. Frame 1202 may be adapted for ease of use and manufacture. For example, frame 1202 may include a base 1208 to facilitate handling and/or stacking, and frame 1202 may include notches 1210 to facilitate receiving a protective lid. Frame 1202 may be constructed of a material, such as a thermoplastic, that is sturdy enough for repeated, rugged use and yet minimally photoluminescent to reduce background upon illumination.

Transport module 2100 has two I/O sites, from which plates are taken and/or added at the bottom. Typically, but not necessarily, one of these sites is dedicated to input, and the other is dedicated to output. To input a plate, a robot (1) removes a plate from the bottom of an input stack of plates at the input site, (2) transports the plate to the transfer site, and (3) transfers the plate at the transfer site to a transport mechanism

for an associated function module. To output a plate, the robot (1) takes the plate from the transport mechanism for the function module at the transfer site, (2) transports the plate to the output site, and (3) transfers the plate at the output site to the bottom of an output stack of plates at the output site. In transport module 2100, these functions are performed by the intersite and intrasite drivers, with preferred throughputs ranging from about 1 second per plate to about 5 seconds per plate.

Dispense-element array 3316 may be used to dispense individual measured aliquots of fluid onto or into a sample holder. For example, the array may be used to dispense into some or all of the wells 3318 in microplate 3308 by aligning the array with the wells and dispensing. If there are more sample wells than dispense elements, dispensing can occur in steps by dispensing to a first set of wells 3322, moving the dispense array and microplate relative to one another (for example, along a Y-axis, perpendicular to X-axis), and then dispensing to a second set of wells 3324. This process may be repeated for additional sets of wells 3326 as necessary.

Each bank of dispensers can be independently installed or de-installed into a to standard slot arrangement. With this slot arrangement, banks of dispense tips with different dispense characteristics (e.g., number of tips, volume range, or other functions such as plate washing) may be installed in a mix and match fashion. Software can be configured for the type of module that has been installed into each slot, and programmed accordingly. For example, microplate washing can be implemented by changing the design and programming of each bank of dispense elements. With proper design and sizing, one bank of dispense elements can aspirate solution from a column

or row of wells, while another bank can subsequently dispense clean solution. Alternately, for the wash function, a head may contain both dispense and aspirate elements, at different heights, allowing dispense and aspirate without movement of the plate.

A cleaning module generally comprises any mechanism or system for cleaning a sample holder such as a microplate. A cleaning module (or cleaning function) may be integrated with a fluidics module, for example, by alternately aspirating and dispensing cleaning and rinsing fluids with the dispense elements. Alternatively, a cleaning module may be a stand-alone system, for example, having a washer, a dryer, and an outlet.

FIG. 48 shows such an integrated system 4500, which may be used to process and analyze a sample contained in a microplate. System 4500 includes a microplate input site 4502, a fluidics module 4504, an incubation module 4506, and an analysis module 4508. A transport module 4510 transports microplates from site to site. A microplate 4512 is singulated from the bottom of a stack in input site 4502. Transport module 4510 transports the microplate to fluidics module 4504, where fluid is added to wells in the microplate. The microplate 4512 is then transported and stacked in incubation module 4506, along with other microplates and intervening spacers and lids in accordance with previously described embodiments of the invention. After the samples are incubated in incubation module 4506, the microplate may be singulated from the bottom of a stack in the incubation module and transported to analysis module 4508 where a test is performed on the sample.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by 6,325,114 Bivert et al.

Bivert et al. disclose an apparatus and method for increasing the rate at which microwell plates can be manipulated in performing various experiments. Namely, this invention relates to an apparatus and method of performing a pipetting operation on multiple microwell plates (tray) in a compact area.

FIG. 1 shows a system for performing various sample analysis protocols. In this embodiment, modules of an automatic laboratory system are placed on table 13. Five plate stackers 50 are shown, although any number of stackers required for a particular protocol can be used. These stackers are used to store microwell plates as described in copending U.S. patent application Ser. No. 09/303,381 U.S. Pat. No. 6,193,102 entitled "Plate Stacker Apparatus" by Bevirt and Brinton filed on Apr. 20, 1999, issued on Feb. 27, 2001 incorporated by reference in its entirety herein. After stacker 50 prepares a microwell plate for presentation, holder 4 on robot arm 6 (conveyor) is directed to that stacker to lift that microwell plate from stacker 50. At that point, the robot arm 6 can carry the microwell plate to a pipetting station 10 (dispensing mechanism) to dispense small amounts of liquid. Or the robot arm 6 can carry the microwell plate to hotel 2. Hotel 2 can be a heating station (temperature maintaining mechanism). For instance, in some sample analyses, it is required to combine reagents in a controlled environment at a particular temperature which is above ambient temperature. In these instances, hotel 2 acts as an oven in which this reaction may occur.

Hotel 2 could also possess light detectors. In this way, if clear microwell plates were utilized, light could shine one side of the microwell plate in the hotel. Detectors could reside on the hotel positioned on the other side of the microwell plate. These detectors could then determine, for example, the color of the sample in each cavity of the microwell plates.

Hotel 2 could be replaced by any number of components to perform operations needed in a given protocol such as a wash station for a pipette, or stations for mixing, incubating, separating, and the like.

Alternatively, robot arm 6 can carry the microwell plate to the various resting stations 8. Any number of procedures could be performed in this fashion. A barcoding station could be placed on table 13 to barcode the microwell plates. Or a plate washing cell could be placed on table 13. Any number of steps in a biological protocol could be performed. Once one particular microwell plate has had all the steps performed as required by protocol, robot arm 60 can return the microwell plate to a stacker. Once all the microwell plates have gone through the protocol and are returned to a stacker 50, an operator (not shown) can remove the rack from the stacker 50 and take the rack of completed microwell plates to another area for post-processing as required.

7. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Mimura et al. US 6,261,521.

Mimura et al. discloses a system setup for a sample analysis system having a plurality of analysis units placed along a main **conveyor** line prior to its analysis operation.

The system includes analysis units of a dispenser type as indicated in FIG. 2 and of a pipetter type as indicated in FIG. 3 in combination. Analysis units 3A, 3F and 3G of FIG. 1 are dispenser type analysis units having fixed analysis channels and dedicated pipette nozzles for each of a plurality of reagents. Analysis units 3B, 3C, 3D and 3E are a pipetter type analysis unit in which analysis channels are not fixed thereby allowing random access, and a single reagent pipette nozzle is allowed to pipette appropriate reagents sequentially according to designated analysis items.

Analysis units 3A to 3G are provided with sample lines 4A to 4G, respectively, each of which is a dedicated line which has a function to fetch sample rack 1 (tray) which is a holder of sample containers from main conveyor line 20, to move the rack to a sampling position, then to return it to the main conveyor line 20. A rack supply portion 17 has an area sufficient to be able to set a plurality of sample racks 1 therein, and a delivery mechanism to deliver the plurality of sample racks 1 one by one to main conveyor line 20.

Each sample rack 1 supplied from rack supply unit 17 is conveyed by main conveyor line 20, and when any analysis by analysis unit 3A is required, sample rack 1 is transferred to sampling line 4A corresponding to the analysis unit 3A. A predetermined amount of a sample is aspirated using a pipette nozzle of sample pipetter 48a from the sample container on sample rack 1 positioned at its sampling position and is injected into reactor 46a. Into this reactor positioned at a predetermined position on the reactor rows, a reagent corresponding to a specified analysis item is injected to produce a reaction. After a predetermined period of time, a reaction solution

in reactor 46a is subjected to measurement of its optical property using multi wavelength **photometer 15a**. An output signal from multi wavelength photometer 15a is processed by logarithm converter 30a and A/D converter 31a under control of distributed computer 6A of the analysis unit, then it is transmitted to host control computer 40. Dispenser type analysis units (dispense mechanism) 3F and 3G have the same configuration as that of analysis unit 3A.

Now, with reference to FIG. 3, an example of a configuration of an analysis unit having a pipette type reagent supply unit will be described. Within reactors 46b disposed in array on reactor section 5B in analysis unit 3B, reactions are allowed to proceed between samples and reagents specified for particular analysis items. Sample rack 1 transferred from main conveyor line 20 to sampling line 4B (indicated in FIG. 1) is positioned at its sampling position thereon, where using a pipette nozzle of sample pipetter 48b, the sample is aspirated and a predetermined quantity of the sample is injected into reactor 46b. Sample pipetter 48b is provided with sample pipetter pump 47b. Reactor section 5B is kept at a constant temperature (temperature maintaining mechanism) (for example, at 37.degree. C.) by isothermal liquid supplied from an isothermal tank 10.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Watson et al., Kalra et al., Kercso et al. Knobel, Cathcart et al., Masterson et al., Sakuma, Roach et al., Ishihara et al., Taylor et al., Gallagher et al.,

Lewis et al., Parce et al., Matsubara et al., Martinell Gisper-Sauch, Ohishi et al., Mimura et al. (,549), Pfost et al., and Yamashita et al. disclose automated dispensing systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg

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